CLAIMS

1. Use of ethanol as external plasticizer for the preparation of subcutaneous implants wherein the active principle is dispersed in a matrix of PLGA.

2. Use as claimed in claim 1, characterised in that the concentration of said ethanol is between 2 and 15 % by weight on the weight of PLGA.

3. Use of ethanol as claimed in claim 2 wherein said concentration is between 3 and 10% by weight on the weight of PLGA.

4. Use of ethanol as claimed in claim 3 wherein said concentration is between 5 and 10% by weight on the weight of PLGA.

5. Use of ethanol as claimed in claim 4, for the preparation of subcutaneous implants containing thermolabile active principles.

6. PLGA plasticized with ethanol.

7. Plasticized PLGA as claimed in claim 6 containing ethanol in concentrations between 2 and 15 % by weight on the weight of PLGA.

8. Plasticized PLGA as claimed in claim 8 wherein said concentrations are comprised between 3 and 10% by weight on the weight of PLGA.

9. Plasticized PLGA as claimed in claim 8 in which said concentrations are between 5 and 10% by weight on the weight of PLGA.

10. Process for preparing the plasticized PLGA in accordance with any one of claims 6-9 comprising the following stages

a) grinding PLGA to obtain a ground product in which the particles have dimensions less than 250 μm;

b) adding ethanol to the ground product obtained in the preceding stage in concentrations between 5 and 20 parts by weight/weight of PLGA and heating the mixture obtained to a temperature between 45 and 65°C, until a viscous and stable gel is obtained;

c) drying the product coming from step (b),

d) grinding the dried product obtained at a temperature ranging from –20 and +5°C;

e) optionally mixing the product originating from the preceding stage with PLGA as such which has been previously ground until a ground product of particle size less

than 250 μm is obtained, in weight ratios between 10:90 and 99:1, at a temperature between –20 and +5°C,

f) extruding the aforesaid mixture at 75°C,

g) grinding the extruded product at a temperature between -20°C and +5°C.

11. The process as claimed in claim 10 characterised in that in stage (b) the ethanol is added in a quantity of 10 parts by weight/weight of PLGA.

12. Process as claimed in any one of claims 10-11, characterised in that the drying in stage (c) is conducted until obtaining an ethanol concentration in PLGA comprised between 10 and 30%/by weight/PLGA weight.

13. Process as claimed in claim 12 wherein said ethanol concentration is 20% by weight/PLGA weight.

14. Process according to claim 12 or 13, characterised in that said drying is carried out at a temperature comprised between 20 and 25°C under an air stream.

15. The process as claimed in any one of claims 10-14, characterised in that the grinding temperature in stage (d), (e) and (g) is -10°C.

16. Process as claimed in any one of claims 10-15, characterised in that in stage (e) the weight ratio of PLGA originating from stage (d)/PLGA as such is comprised between 16:84 and 40:60.

17. Subcutaneous implants containing the active principle dispersed in PLGA plasticized with ethanol as claimed in any one of claims 6-9.

18. Subcutaneous implants as claimed in claim 17 containing thermolabile active principles dispersed in plasticized PLGA as claimed in anyone of claims 6-9

19. Subcutaneous implants as claimed in claim 18, characterised in that said thermolabile active principles are chosen from the class consisting of: proteins, vaccines, antibodies and vectors for genic therapy.

20. Process for preparing the subcutaneous implants as claimed in any one of claims 17-19 comprising the following stages:

i) mixing the active principle with the plasticized PLGA as claimed in any one of claims 6-9, at a temperature between -20°C and +5°C,

ii) extruding the ground product originating from stage (i) at a temperature less than 70°C.

21. Process as claimed in claim 20, characterised in that the temperature of stage

(i) is -10°C.

22. Process as claimed in any one of claims 20-21 characterised in that the temperature of stage (ii) is less than 60°C when plasticized PLGA containing ethanol at concentrations between 3 and 4% by weight on the weight of PLGA is used in stage (i).

23. Process as claimed in any one of claims 20-22 characterised in that the temperature of stage (ii) is equal to 40°C, when plasticized PLGA containing ethanol at concentrations between 5 and 10% by weight/ weight of PLGA is used.